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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,639	03/10/2004	David O'Connor	2500495-991101	6690
26379	7590	07/29/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP			LIU, SUE XU	
2000 UNIVERSITY AVENUE			ART UNIT	
E. PALO ALTO, CA 94303-2248			PAPER NUMBER	

1639

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,639

Applicant(s)

O'CONNOR ET AL.

Examiner

Sue Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-82 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26, drawn to a device comprising a substrate, classified variously, for example, in class 435, subclass 283.1.
 - II. Claims 27-54, drawn to a device comprising an array of microwells, classified variously, for example, in class 435, subclass 294.1.
 - III. Claims 55-60, drawn to a method of forming an array of microwells in a substrate, classified variously, for example, in class 435, subclass 287.1.
 - IV. Claims 61-65, drawn to a method of simultaneously conducting a plurality of chemical reactions, classified variously, for example, in class 435, subclass 7.5.
 - V. Claims 66-70, drawn to a method of detecting an analyte in a plurality of test samples, classified variously, for example, in class 435, subclass 7.1.
 - VI. Claims 71-76, drawn to a method of assembling a plurality of compounds, classified variously, for example, in class 536, subclass 25.3.
 - VII. Claims 77-82, drawn to a kit comprising of a device and a reaction component, classified variously, for example, in class 435, subclass 290.3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions Groups III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups III-VI drawn to various methods. The methods are independent because they use different steps, require different reagents and/or will produce different results. Group III invention directs to a method of forming an array of microwells in a substrate, and requires the steps and/or reagents of “selectively leaching defined areas,” and “selectively etching defined areas,” which are not required by the methods recited in Groups IV-VI. Group IV method of conducting a plurality of chemical reactions requires various steps and/or reagents such as ligations reagents, which are not required by other Groups (III, V, and VI.) Likewise, Group V method of detecting an analyte in a plurality of samples requires various steps and/or reagents such as “forming a complex between the probe and the analyte,” which are not required by any of the other Groups (III, IV, and VI). Group VI method of assembling a plurality of compounds recites various required steps and/or reagents such as “adding a first component...adding a second component...”, which are not required by any of the other Groups (III, IV and V). Thus, inventions of Groups III-VI are independent from each other, and restriction between the groups is proper.

3. Inventions of Groups I, II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Group I, II and VII drawn to different products. The products are distinct because they have different functions and/or structures. Both Groups II and VII products require “a cavity located at a side of the substrate opposite the first side,” and “the porous region...is formed by selectively removing at least one constituent of the substrate” (see

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Claims 27 and 77), which are not required by Group I product. Group II product also requires “a reagent used in a oligonucleotide synthesis reaction,” which is neither required by Group I nor Group VII. Group VII product requires “a reaction component”, which is not required by Group I, and is structurally and functionally different from Group II requirements. Thus, the products of Group I, II and VII are distinct from each other, and restriction between the groups is proper.

4. Inventions of Group III and Groups (I, II, and VII) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the invention of Group III method can be used to make distinct and different products of Group I, II and VII. Thus, restriction between the groups is proper.

5. Inventions of Groups (I, II and VII) and Groups (IV-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the method group of (IV-VI) can be practice with any of the product groups (I, II and VII). Since the methods of Groups (IV-VI) are independent, and the products of Groups (I, II, and VII) are shown to be distinct as described above, the inventions of Groups I, II, and IV-VII are distinct from each other. Thus, restriction between the groups is proper.

6. Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent

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subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following 18 sets of patentably distinct species of the claimed invention. Applicants are requested to further elect a single ultimate species for each of the following:

- A.) A single specific species of a “substrate”. (e.g. borosilicate glass.)
- B.) A single ultimate size of pores selected from the range of 2.5 to 60.0 nanometer. (e.g. 7.5 nanometer.)
- C.) A single ultimate species of organothiol molecules. (e.g. alkylthiol.)
- D.) A single ultimate species of metallic layer. (e.g. gold.)
- E.) A single ultimate species of electrode material selected from the following: aluminum, gold, silver, tin, copper, platinum, palladium, carbon, **OR** semiconductor materials. If applicants elected semiconductor materials, a single ultimate species of semiconductor material is requested.
- F.) A single ultimate species of conductive material selected from the following categories: epoxy, electroless nickel plating, conductive gel, **OR** conductive polymer.

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Applicants are further requested to select a single specific species from the elected category. (e.g. silver epoxy.)

G.) A single species of "containment layer" selected from either the categories of hydrobic OR hydrophilic. Applicants are further requested to select a single specific species from the elected category.

H.) A single specific species of marker. (e.g. optical bar code.)

I.) A single species of reflective surface. (e.g. aluminum)

J.) A single species of nonreflective surface. (e.g. plastic)

K.) A single species of chemical reactions selected from ligation reactions, primer extension reactions, nucleotide sequencing reactions, restriction endonuclease digestions, biological interactions, oligonucleotide synthesis reactions, OR polynucleotide hybridization reactions. If applicants elect biological interactions, applicants are further requested to elect a single ultimate species from avidin-biotin interactions, antigen-antibody interactions, enzyme-substrate reactions, OR ligand-receptor interactions.

L.) A single number of components of a chemical reaction immobilized to the porous region. (e.g. 3 components.)

M.) A single ultimate species of a leachant. (e.g. H_2SO_4)

N.) A single ultimate species of a etchant. (e.g. hydrofluoric acid solution.)

O.) A single ultimate species of a mask.

P.) A single species of a test sample selected from a bodily fluid, a suspension of

solids in an aqueous solution, a cell extract, OR a tissue homogenate. If applicants elect bodily fluid, applicants are further requested to select a single ultimate species from the following: urine, blood, plasma, serum, saliva, semen, stool, sputum, cerebral spinal fluid, tears, OR mucus.

Q.) A single ultimate species of probe selected from the following categories: small molecules, organic functional groups, biomolecules, metals, metal chelates, OR organometallic compounds. Applicants are further requested to elect a single specific species from the elected category. (e.g. polynucleotide for the category of biomolecules.)

R.) A single ultimate species of compound selected from peptides OR oligonucleotides.

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. No matter which group Applicants elect, Applicants should identify which claims they believe are generic for each of the corresponding species sets A.)-R.), and which claims read on a particular species within the species sets A.)-R.) For example, Applicants' reply might state "...claim X is generic to the elected species of species sets A.), C.) and E.), but reads on the particular elected species for species sets B.) and D.)" Should a given species not pertain to Applicants' elected group, Applicants should indicate accordingly. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is further reminded that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sue Liu
Art Unit 1639
7/22/05


PADMASHRI PONNALURI
PRIMARY EXAMINER